UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,405	11/30/2004	Wolfgang Demmer	9013.0099	2828

7590 02/07/2008

Attn: Dennis E. Stenzel, Esq.
Chernoff, Vilhauer, McClung & Stenzel, LLP
Suite 1600
601 S.W. Second Avenue
Portland, OR 97204-3157

EXAMINER	
FERNANDEZ, SUSAN EMILY	
ART UNIT	**PAPER NUMBER**
1651	

MAIL DATE	DELIVERY MODE
02/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,405	DEMMER ET AL.	
	Examiner	Art Unit	
	Susan E. Fernandez	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-16* is/are pending in the application.

4a) Of the above claim(s) *1-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 13-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 5, 2007, has been entered.

Claim 12 is cancelled. Claim 16 is new. Claims 1-11 and 13-16 are pending. Claims 1-10 are withdrawn.

Claims 11 and 13-16 are examined on the merits to the extent they read on the elected subject matter and species.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is rendered indefinite by the recitation "a functionalized microporous membrane body containing functional groups *capable of* chemically coupling with protease inhibitors..." (emphasis added). It is unclear from the phrase "capable of" that the protease inhibitors are actually chemically coupled with the functional groups, though it appears that the membrane should comprise of protease inhibitors in order to serve in a device for removing

proteases from biological fluids and pharmaceutical solutions. Given the use of the phrase "capable of," the membrane does not necessarily comprise of protease inhibitors. Thus, claims 11 and 13-16 are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grano et al. (International Journal of Artificial Organs, 2002, 25(4): 297-305) in view of Burtin et al. (US 6,248,238) and Bergmann (US 5,168,041).

Grano et al. discloses a membrane loaded with antiproteases for reducing the active protease blood concentration (abstract), wherein a protease/antiprotease complex is formed upon

contacting the membrane with a solution containing proteases (page 298, first column, first paragraph). An antitrypsin is immobilized via diazotization occurring through tyrosine residues (page 299, first column, first full paragraph and Figure 1). Thus, the protease inhibitor (antitrypsin) is coupled to the membrane body via functional groups, where nonionic chemical bonding occurs. Further still, it is noted that trypsin is a serine protease (page 300, second column, second paragraph under "Results").

Grano et al. differs from the claimed invention in that it does not expressly disclose a device having a housing with a fluid inlet and a fluid outlet comprising a plurality of membranes.

Burtin et al. discloses a medical apparatus for the extracorporeal treatment of blood or plasma, comprising a semi-permeable membrane with protease inhibitors (column 4, lines 34-36). The apparatus clearly comprises a housing having a fluid inlet and a fluid outlet (see Figure 5).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have used the Grano membranes in a series in a medical apparatus for the extracorporeal treatment of blood. One of ordinary skill in the art would have been motivated to do this since Burtin et al. demonstrates that protease inhibitors on membranes in a housing with a fluid inlet and a fluid outlet is suitable for treatment of blood. Further more, the use of multiple membranes in a series would have ensured thorough reduction of the active protease blood concentration.

Additionally, Grano et al. does not expressly disclose using different protease inhibitors in each of the membranes of the device, that each membrane contains two different protease

inhibitors, or that the protease inhibitors are any of the compounds (pepstatin and the elected species) recited in instant claim 13.

Bergmann lists various protease inhibitors on Table 1 at column 4, where the table includes pepstatin and the elected species recited in instant claim 13.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have used different compounds as the protease inhibitors present in the membranes of the device, where the different compounds may be present in different membranes and/or combined with other protease inhibitors in the same membrane. One of ordinary skill in the art would have been motivated to do this in order to have separated a variety of proteases from a solution, or to have ensured that a specific protease is indeed separated from a solution. It would have been obvious to have used compounds recognized in the art as protease inhibitors, such as those listed in Table 1 at column 4 of Bergmann, in the device, as Grano et al. does not limit the protease inhibitor included in its membranes. Thus, claims 11 and 13-15 are also rendered obvious.

Claims 11, 13, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charcosset (J. Chem. Technol. Biotechnol. 1998. 71: 95-110).

Charcosset discloses Sartobind epoxy membrane which is made by Sartorius (Table 1 on page 99). It is noted that this is the membrane disclosed in Examples 1 and 2 in the instant specification as a suitable regenerated cellulose functionalized (epoxy-activated) microporous membrane (page 5, lines 16-17 and page 6, line 14) for the practice of the claimed invention. Therefore, the Sartobind epoxy membrane contains functional groups (epoxy groups) capable of

chemically coupling with inhibitors of acid proteases, metalloproteases, cysteine proteases, and serine proteases. Note that Charcosset teaches a configuration in which the feed solution flows through the membrane (page 95, first paragraph), thus a housing having a fluid inlet and outlet is taught.

Although the reference does not specifically teach that the composition is effective for removing proteases from a fluid, the compositions are the same, thus the claimed function must be inherent to the reference composition. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. As pointed out in MPEP §2112, "the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable". Given that the membrane is capable of binding protease inhibitors, it is capable of removing proteases from a solution.

Charcosset differs from the claimed invention in that it does not teach that there are a plurality of membranes arranged therein in series in the device. However, one of ordinary skill in the art would have been motivated to have including a plurality of membranes in the device since the use of multiple membranes in a series would have ensured more thorough protein purification. The presence of multiple membranes would have yielded the predictable result of improving protein purification. Moreover, MPEP 2144.04 teaches the obviousness of the duplication of parts (see Section VI, Part B.).

Thus, a holding of obviousness is clearly required.

Response to Arguments

Applicant's arguments filed November 5, 2007 (July 16, 2007) have been fully considered but they are not persuasive. The applicant requests that the finality of the previous office action be withdrawn since the applicant asserts that the amendment of January 12, 2007, did not necessitate the new ground of rejection over Grano et al. However, it is respectfully noted that the recitation that the coupling is specified as being by a nonionic chemical bond necessitated the new ground of rejection. Thus, the finality of the previous office action has been maintained.

Applicant also asserts that Grano et al. does not teach any of the chemistry necessary to bind any of the four specific types of protease inhibitors which are recited in claim 11. However, since known chemical structures are being dealt with, the ability to bind the inhibitors to the membranes would have been within the purview of the skilled artisan. Moreover, it is even noted that the disclosure as filed does not describe the chemistry necessary to bind all four specific types of protease inhibitors recited in claim 11.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan E. Fernandez
Assistant Examiner
Art Unit 1651

Leon B. Lankford, Jr.
Primary Examiner
Art Unit 1651

sef